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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,978	11/12/2008	Reiko Matsuyama	MATSUYAMA 2	8121

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EXAMINER	
MONSHIPOURI, MARYAM	

ART UNIT	PAPER NUMBER
1656	

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10/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,978	MATSUYAMA ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-46* is/are pending in the application.

4a) Of the above claim(s) *28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-27 and 29-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/14/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's response to restriction letter of 8/7/09 is acknowledged. Applicant elected a method of use of a baculovirus p35 gene or a host cell comprising it for mass producing a protein by culturing a host cell comprising said p35 gene together with the following species CHO cells and chicken beta-actin promoter, with traverse.
In traversal of restriction requirement applicant argues the following: That claims 1-2 are generic and the inventions listed as (a)-(e) in the previous office action all share a special technical feature and the examiner has cited no art which breaks unity of invention. Therefore, restriction requirement should be withdrawn.

These arguments were fully considered but were found **unpersuasive**. Firstly the examiner maintains that she does not necessarily need to cite prior art in order to establish lack of unity. Applicant is well aware that each of downstream caspase inhibitors of Groups a-e (see previous office action) have structures and even functions that share no special technical features. Secondly applicant is invited to review Lin et al. (In Vitro Cell Dev. Biol.-Animal, 37, 293-302, 2001 (cited in the IDS and in the following office action) which does teach an insect Sf9 cell transformed with baculovirus p35 gene which displays enhanced glycoprotein production and secretion prior to this invention, which clearly brakes the unity of invention.

Therefore, the examiner does not find any reason to withdraw lack of unity, which is maintained and is hereby made **Final**.

DETAILED ACTION

Claims 24-27, 29-46, drawn to a recombinant animal cell transformed with baculovirus p35 gene and a method of use thereof for recombinant expression of target

proteins (and the following species CHO cells and chicken beta actin promoter) are under examination on the merits. Claim 28 and all inventions of Groups (b)-(e) and all other species recited in the previous office action are withdrawn.

Priority

It is noted that the oath (declaration) of this case refers to a PCT and a couple of Japanese priority applications. Applicant is required to introduce the claimed priority data at the first page of the disclosure in response to this office action.

Specification

The disclosure is objected to for reciting hyperlink language (see page 21, for example) . Applicant is advised to delete hyperlink language from the text everywhere in the disclosure (see MPEP 608.01).

Claim Objections

Claims 24-27, 29-46 are objected to because of the following informalities: said claims appear to be a word to word translation of Japanese to English and are very difficult to understand. Applicant is advised to rewrite said claims in clear and concise English. Appropriate correction is required.

Claim 27 is objected to because of the following informalities: said claim still recites non-elected subject matter such as “cowpoxvirus crmA gene, a herpevirus-derived v-FLIP gene etc. Applicant is advised to delete non-elected subject matter from said claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-26 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “production amount potentiating factor “ is vague and indefinite. It is unknown what is a “production amount” and what is a “potentiating factor”. Appropriate clarification is required.

Claims 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what “caspase activity inhibiting activity” and “potentiating action” mean.

Claims 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “ protein biosynthesis activity” is vague. It is unknown which specific activity said phrase is referring to.

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Markush language in said claim repeats the word “and” twice and is confusing. Additionally the phrase “ the production gene is one selected from a fibrinogen gene, an ecarin gene and a factor VIII gene, and the gene encoding the production amount potentiating factor is baculovirus” does not make sense.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. It is unknown what "the protein highly producing recombinant animal cell " mean. Said phrase also lacks antecedent basis.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what "highly produced with the use of " mean. In other words it is unknown what the difference between produced and "highly produced" is. Appropriate clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-27, 35, 41, 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. "Lin" (IN Vitro Cell. Dev. Biol-Animal, 37, 293-302, 2001, cited in the IDS). Lin teaches an insect Sf9 cell transfected with a "potentiating factor", namely baculovirus p35 gene or derivatives thereof (inherently having caspase inhibiting activity) which displays higher secreted glycoprotein production rates when grown in serum free medium (see abstract , figures 2-4 and pages 298-299), anticipating claims 24-27, 35, 41 and 46 of this invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-34, 36-40, 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (cited above) in view of Hui et al. "Hui" (US patent No. 6,187,588 issued 2/13/2001). As stated above, Lin teaches an animal cell transformed with baculovirus gene, which when grown under optimal fermentation conditions (cell growth conditions) when apoptosis is not induced displays higher production rates for secreted recombinant glycoprotein expression. Lin does not teach CHO cells transformed with said p35 gene.

Hui teaches a method of increasing the efficiency of transfection of cells by incubating them with a caspase inhibitor (see column 5) such as Baculovirus p35 gene wherein said cells can include CHO cells (see Example 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to start with the p35 gene transformed Sf9 cell of Lin and substitute said host cell with the CHO cell of Hui using a variety or promoters such as or including a chicken beat actin promoter before growing said transformed CHO host cell under optimal large scale growth conditions (which inherently include fed batch culture conditions yielding up to 4 mg/ml of final product), optionally in serum free medium as taught by Lin, in order prepare large quantities of a desired polypeptide.

One of ordinary skill in the art is motivated in replacing the host cell of Lin with the CHO cell of Hui because such host cell is mammalian, well characterized and is

capable of recombinantly expressing proteins that for example require post translational modifications such as blood factors, ecarin, fibrinogen etc.

One of ordinary skill has a reasonable expectation of success in preparing recombinant CHO cells of Lin in view of Hui, because methods of cell transfection with two separate genes (i.e. P35 gene and desired polypeptide encoding gene) simultaneously or one at the time (before growing them according to large scale fermentation conditions) are fully established in the prior art and both Hui and Lin teach that caspase inhibitors such as Baculovisrus P35 gene product or its encoding DNA, improve the yield of recombinant protein expression, rendering the invention obvious.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

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